Title: CHANGE LOG FOR IMPLANTABLE MEDICAL DEVICE

#### REMARKS

In response to the Office Action mailed on February 17, 2004, and the references cited therewith, no changes to the claims were made; as a result, claims 22-33 and 35-43 are pending in this application.

# §112 Rejection of the Claims

Claims 22-32, 42 and 43 were rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the Office Action asserts that the subject matter not described in the specification is the means or step for detecting an accidental change in the first state of the at least one programmable parameter to a second state.

Applicant respectfully traverses the rejection. The specification describes a test whether the parameter values and/or states are within acceptable ranges (see page 10 line 15 of the specification). The specification also refers to parameter values and/or states that are not within acceptable ranges as errors (see page 10 line 19 of the specification). One skilled in the art would understand upon reading the specification that an accidental change would be a change that produced an error. The integrity tests describe a means or step for detecting an accidental change (see specification page 10 lines 8-21 and page 11 line 4-5). Applicant respectfully requests reconsideration and allowance of claims 22-32, 42 and 43.

## §102 Rejection of the Claims

Claims 22, 24, 26, 42 and 43 were rejected under 35 USC § 102(e) as being anticipated by Er et al. (U.S. Patent No. 5,974,341, "Er"). Applicant respectfully traverses the rejection.

Applicant does not admit that Er is prior art and reserves the right to swear behind Er at a later date. Nevertheless, Applicant believes that the present application is distinguishable from Er for the reasons stated below.

Concerning claims 22, 24, 26, 42 and 43:

Applicant is unable to find in Er, among other things,

detecting an accidental change in the first state of the at least one programmable parameter to a second state; and storing in the parameter log the first state of the at least one programmable parameters accidentally changed to the second state,

as recited or incorporated in claims 22, 24, and 26. Neither is Applicant able to find means for performing the method as recited or incorporated in claims 42 and 43. The Office Action asserts that Er detects any change made to the automatic switching mode and will inherently detect an accidental change. However, the automatic switching mode is apparently only a recorded and displayed event. Applicant is not able to find any disclosure in Er of detection of the automatic switching, let alone a disclosure of detection if the automatic switching is accidental.

Additionally, the Office Action only asserts that Er will inherently detect an accidental change without offering support for the assertion. Applicant respectfully traverses the assertion of inherency because the fact that a certain result may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic; a rationale or evidence tending to show inherency must be provided. Further, in relying upon the theory of inherency, the examiner must provide a basis in fact and/or reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (M.P.E.P. § 2112). Applicant respectfully submits that the examiner has not produced extrinsic evidence to show that the element of detecting an accidental change in the first state of the at least one programmable parameter to a second state, as recited or incorporated in the claims, is necessarily present in Er.

Applicant respectfully requests reconsideration and allowance of claims 22, 24, 26, 42 and 43.

# §103 Rejection of the Claims

Claims 23 and 26-32 were rejected under 35 USC § 103(a) as being unpatentable over Er et al. (U.S. Patent No. 5,974,341). Applicant respectfully traverses the rejection.

Claims 23, and 26-32 ultimately depend on claim 22 and are believed to be allowable at least for the reasons stated previously for that claim.

Additionally, the Office Action admits that Er does not disclose the detection of accidental change of different parameters ... and recording execution of an integrity correction program such as recited in claims 23, 26-32 (see Office Action page 4 \( \text{92} \)). The Office Action asserts the missing elements would have been obvious to one of ordinary skill in the art at the time the invention was made, but does not provide any documentary evidence to support the assertion. Because the elements recited in the claims are not found in Er, Applicant assumes the Office Action takes official notice of the missing elements without documentary evidence to support the official notice conclusion.

Applicant respectfully traverses the assertion of Official Notice without documentary evidence. Official notice unsupported by documentary evidence should only be taken where the facts asserted to be well known, or to be common knowledge in the art are capable of instant and unquestionable demonstration of being well known (see M.P.E.P. § 2144.02 (A)). Applicant submits that detecting the accidental changes of different parameters recited in the contested claims, storing the accidental changes in the parameter log and recording execution of an integrity correction program as recited in the contested claims does not meet the required standard of being capable of instant and unquestionable demonstration of being well known.

Applicant respectfully requests that the next official communication cite references in support of the assertion of Official Notice.

#### Claim 25

Claim 25 was rejected under 35 U.S.C. § 112 but was not rejected for anticipation under § 102(e) or for obviousness under 35 U.S.C. 103(a). Applicant assumes that claim 25 is allowable if the § 112 rejection is overcome. Applicant respectfully requests clarification in the next official communication.

Serial Number: 10/010845 Filing Date: November 13, 2001

Title: CHANGE LOG FOR IMPLANTABLE MEDICAL DEVICE

#### Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 349-9587 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

ALLAN T. KOSHIOL ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402-

(612) 349-9587

Date / June 19

Timothy B Clise

Reg. No. 40,957

<u>CERTIFICATE UNDER 37 CFR 1.8:</u> The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, MS: Amendment, P.O. Box 1450,

Alexandria, VA 22313-1450, on this \_\_\_\_\_\_ day of <u>June</u>, 2004.

Name

Signature